

Amendment and Response

Applicant: Jack D. Lemmon

Serial No.: 10/688,718

Filed: October 17, 2003

Docket No.: M190.143.101

Title: PROSTHETIC HEART VALVE SIZER ASSEMBLY WITH FLEXIBLE SIZER BODY

REMARKS

The following remarks are made in response to the Non-Final Office Action mailed March 18, 2005 ("OA 3-18-05"). In that Office Action, the Examiner withdrew claims 4-7, 14, 23, 29, and 31-37. Claims 1-3, 8-10, 12-13, 15-21 were rejected under 35 U.S.C. §102(b) as being clearly anticipated by Rhee, U.S. Patent No. 6,350,281 ("Rhee"). Claims 11, 22, and 24 were rejected under 35 U.S.C. §103(a) as being unpatentable over Rhee. Claims 27-28 were rejected under 35 U.S.C. §103(a) as being unpatentable over Rhee in view of Love et al., U.S. Patent Application Publication No. 2002/0020074 ("Love").

With this Response, claims 1, 8, and 20 have been amended; claims 32-37 cancelled; and newly presented claim 38 added. Claims 1-31 and 38 are pending in the application and are presented for consideration and allowance.

Objection to the Specification

The Examiner objected to the specification on the basis that it failed to provide a proper antecedent basis for the claimed subject matter. The Examiner requested correction of "annular housing (describing a sizer) and stent." OA 3-18-05 at 3. Following a good faith review of the application, it is believed that the terms "annular housing" and "stent" are properly used to describe exemplary heart valves, not "a sizer" as indicated by the Examiner. In particular, the term "stent" is used in association with prosthetic heart valves, such as bioprosthetic heart valve 30 illustrated in Fig. 2A. Spec. at p. 7, ll. 5-7. In turn, the term "annular housing" is used in association with mechanical heart valves, such as mechanical heart valve 74 shown in Fig. 6A. Spec. at p. 17, ll. 1-2. In contrast, Fig. 2C is a perspective view of a sizer. Spec. at p. 5. The terms "stent" and "annular housing" are defined with sufficient clarity to one having ordinary skill in the art. For example, an exemplary stent designated by reference numeral "32" is described at least at p. 7, ll. 8-9 as well as FIG. 2A. Additionally, an exemplary annular housing, designated by reference numeral "78" is described at least at p. 17, ll. 1-11 and p. 18, ll. 4-6 as well as FIG. 6A. In light of the descriptions in the specification and drawings and the knowledge afforded to one having ordinary skill in the art, it is believed that no further amplification of the

Amendment and Response

Applicant: Jack D. Lemmon

Serial No.: 10/688,718

Filed: October 17, 2003

Docket No.: M190.143.101

Title: PROSTHETIC HEART VALVE SIZER ASSEMBLY WITH FLEXIBLE SIZER BODY

description of these terms is necessary according to either MPEP §608.01(o) or 37 C.F.R. 1.75(d)(1). Withdrawal of the Examiner's rejection on such grounds is respectfully requested.

Examiner's Withdrawal of Claims 4-6 as Drawn to a Non-elected Group/Species

The Examiner indicates that claim 4, including limitations relating to a stent, "reads on the non-elected embodiment shown in figure 2C." The description and illustration of Fig. 2C are descriptive of a sizer, not a prosthetic heart valve having a stent. Spec. at p. 11, ll. 19-29. Flexible leaflet prosthetic heart valves are generally categorized as having a frame or stent or as having no stent. In other words, the limitations of claim 4 relating to a stent indicate the type of "prosthetic heart valve including an annular extension having a first flexibility and a sewing ring having a second flexibility." However, the sizer embodiments applicable to prosthetic heart valves having an "annular extension including a stent" are not limited to the embodiments described in association with Fig. 2C. As such, it is believed the withdrawal of claims 4-6 from examination is improper. Appropriate action for examination of claims 4-6 is respectfully requested.

Claim Rejections under 35 U.S.C. §§102, 103

The Examiner rejected claims 1-3, 8-13, 15-22, 24-26, and 30 under either 35 U.S.C. §102(b) as being clearly anticipated by Rhee, or under 35 U.S.C. §103(a) as being unpatentable over Rhee. For at least the reasons described below, the cited references fail to teach or suggest the limitations of those claims.

In particular, independent claim 1 as amended relates, in part, to a flexible sizer body comprising an annular wall coupled to and extending from an outer ring, wherein the annular wall forms a plurality of extremities adapted to be inwardly deflected. Independent claim 20 as amended relates, in part, to a sizer assembly comprising a flexible sizer body including an annular wall coupled to and extending from an outer ring, wherein the annular wall forms a plurality of extremities configured to deflect inwardly. As noted by the Examiner, Rhee "fails to teach [an] annular wall [that] forms a plurality of extremities." OA 3-18-05 at 6. While the legs 2 or 16, 18 of Love may be "extremities," these legs 2, 16, 18 do not teach the limitations of

Amendment and Response

Applicant: Jack D. Lemmon

Serial No.: 10/688,718

Filed: October 17, 2003

Docket No.: M190.143.101

Title: PROSTHETIC HEART VALVE SIZER ASSEMBLY WITH FLEXIBLE SIZER BODY

“configured to deflect inwardly.” Love, in fact, teaches away from such limitations. In particular, Love teaches an assembly that appears to deflect outwardly or at the very least does not deflect inwardly. See Love at Figs. 1 and 2. Furthermore, Love teaches that legs 16 and 18 maintain predetermined shapes and distances so that Love’s sizers can be used to “compar[e] the curved legs 2 with the native valve geometry” See, e.g., Love at paras. 19-21, 24, & 27. In other words, the Love sizer structure is compared to the actual heart structure to evaluate how the heart’s structure is different from known dimensions associated with the sizer. Thus, taken as a whole, Love fails to teach or suggest a plurality of extremities adapted to be inwardly deflected or a plurality of extremities configured to deflect inwardly as is otherwise required by the limitations of claims 1 and 20. In fact, the purpose of comparing the sizer legs 2 to the “normal native valve leaflet anatomy” teaches away from such limitations as Love does not seek to “‘mimic’ more accurately how the artificial heart valve will be received” but instead seeks to “mimic” how a normal native valve would appear. See OA 3-18-05 at 6 & Love at para. 5. This naturally flows from the fact that the sizer of Love is used as part of a valve reconstruction surgery that does not entail implantation of a prosthetic heart valve. Love at para. 3. Thus, the goals of Rhee and Love are entirely unrelated, dictating that a suggestion to combine is absent.

In light of the above, none of the cited references either alone or in combination teach or suggest the limitations of independent claims 1 or 20 as amended. Claims 2-19 and 21-31 depend, in some form, from independent claims 1 and 20 as amended. Therefore, they are believed to present patentably distinct material from the cited references for reasons similar to those described above in association with independent claims 1 and 20 as amended. As such, the Examiner’s rejection of claims 1-31 is believed traversed. It is respectfully requested that the Examiner withdraw rejection of those claims with allowance and notice to that effect provided.

Newly Presented Claim 38

New claim 38 is presented for consideration and allowance. Support for new claim 38 is believed to be provided by the previously presented claims as well as the specification at the paragraph beginning on page 20, line 8 and Figure 8. The Examiner previously indicated that handle 12 of Rhee teaches or suggests a “cylindrical handle fully capable of meeting the

Amendment and Response

Applicant: Jack D. Lemmon

Serial No.: 10/688,718

Filed: October 17, 2003

Docket No.: M190.143.101

Title: PROSTHETIC HEART VALVE SIZER ASSEMBLY WITH FLEXIBLE SIZER BODY

functional language of sizing.” OA 3-18-05 at 6. New claim 38 relates, in part, to a cylinder sizer having a diameter substantially similar to an opening defined by a valve annulus, wherein the sizer cylinder is coupled with a second end of a handle. It is believed that none of the cited references alone, or in combination, teach or suggest such limitations. Therefore, allowance of newly presented claim 38 with allowance and notice to that effect is respectfully requested.

CONCLUSION

In view of the above, Applicant respectfully submits that pending claims 1-31 and 38 are in form for allowance and are not taught or suggested by the cited references. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 1-31 and 38 is respectfully requested.

No fees are required under 37 C.F.R. 1.16(b)(c). However, if such fees are required, the Patent Office is hereby authorized to charge Deposit Account No. 50-0471.

The Examiner is invited to contact the Applicant’s representative at the below-listed telephone numbers to facilitate prosecution of this application.

Amendment and Response

Applicant: Jack D. Lemmon

Serial No.: 10/688,718

Filed: October 17, 2003

Docket No.: M190.143.101

Title: PROSTHETIC HEART VALVE SIZER ASSEMBLY WITH FLEXIBLE SIZER BODY

Any inquiry regarding this Amendment and Response should be directed to Timothy A. Czaja at Telephone No. (612) 573-2004, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

Dicke, Billig & Czaja, PLLC
Fifth Street Towers, Suite 2250
100 South Fifth Street
Minneapolis, MN 55402

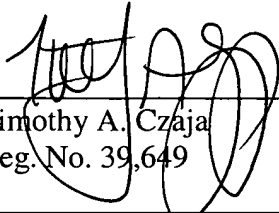
Respectfully submitted,

Jack D. Lemmon,

By his attorneys,

DICKE, BILLIG & CZAJA, PLLC
Fifth Street Towers, Suite 2250
100 South Fifth Street
Minneapolis, MN 55402
Telephone: (612) 573-2004
Facsimile: (612) 573-2005

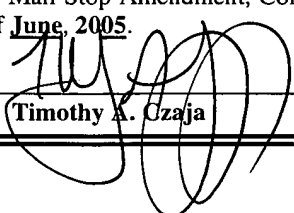
Date: JUNE 16, 2005
TAC:jmc



Timothy A. Czaja
Reg. No. 39,649

CERTIFICATE UNDER 37 C.F.R. 1.8:

The undersigned hereby certifies that this paper or papers, as described herein, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 16th day of June, 2005.

By 
Name: Timothy A. Czaja